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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,506	01/29/2002	Kathleen Kelly	015280-263110US	7612

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/059,506	KELLY, KATHLEEN	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 30, 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *15 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *01/29/02* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II (claims 15 and 16) in the paper received June 30, 2003 is acknowledged.

2. Claims 6-21 are pending.

Claims 6-14 and 17-21, drawn to non-elected inventions are withdrawn from examination.

Claims 15 and 16 are examined on the merits.

Specification

3. The abstract of the disclosure is objected to because it does not contain a concise statement of the technical disclosure of the patent and that, which is new in the art to which the invention pertains, namely an antibody composition.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for those antibodies that bind SEQ ID NO: 1, SEQ ID NO: 2 and SEQ ID NO: 5, which consequently immunologically cross-react with an

antibody that binds the protein of SEQ I D NO: 6, does not reasonably provide enablement for any antibody capable of binding SEQ ID NO: 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicants' claims provide that the claimed antibody composition binds an EGF-like repeat selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 2 and SEQ ID NO: 5 and must be immunologically cross-reactive to an antibody reactive to SEQ ID NO: 6. SEQ ID NO: 1, 2 and 5 are contained with SEQ ID NO: 6. It is clear that an antibody that binds one of the proteins designated as SEQ ID NO: 1, 2 or 5 would be immunologically cross-reactive to an antibody reactive to the protein of SEQ ID NO: 6. These target peptides (SEQ ID NO: 1, 2 and 5) and their corresponding epitopes have been clearly identified and defined. The scope of the claims is not commensurate with the enabling disclosure. Outside the scope of SEQ ID NO: 1, 2 and 5 are the remaining epitopes, which have not been clearly identified. Accordingly the broad claims do not reasonably provide enablement for the myriad of antibodies that must be immunologically cross-reactive to an antibody reactive to SEQ ID NO: 6. The specification fails to provide sufficient guidance to enable one of ordinary skill in the art to make and use any other antibodies that are immunologically cross-reactive to SEQ ID NO: 6 other than the antibodies that bind SEQ ID NO: 1, 2 or 5. Without such guidance, Applicants are only enabled for antibodies that recognize SEQ ID NO: 1, SEQ ID NO: 2 and SEQ ID NO: 5, which inherently bind SEQ ID NO: 6.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 15 is vague and indefinite in the recitation, "specifically reactive, under immunologically reactive conditions". The words, "specifically reactive" suggest the antibody composition elicits some type of reaction, such as a catalytic or endothermic reaction. It is not clear what type of reaction the antibody composition has with the soluble CD97 α subunit. Furthermore, it is not clear what type of parameters or standards govern immunologically reactive conditions wherein the claimed antibody composition reacts with the soluble CD97 α subunits. Accordingly, it is impossible to determine the metes and bounds of the claimed invention.

b. Claim 15 is vague and indefinite in the recitation, "EGF-like". It is not clear if the term "like" is used in reference to the scientific name or is it a general qualifier to broaden to the scope of the claims. Accordingly, it is impossible to determine the metes and bounds of the claimed invention.

c. The recitation "EFG" in claim 15 is vague and indefinite. Applicant is advised to amend the claim with the full terminology following the first citing of "EFG" in the claim.

d. The recitation "unique" in claim 16 is indefinite in that the term is superfluous and does not further clarify the claimed subject matter.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Hamann et al. (The Journal of Immunology 155: 1942-1950, August 15, 1995/ IDS reference A4). Hamann discloses EGF-like domains of CD97 comprising SEQ ID NO: 1, 2 and 5, as well as SEQ ID NO: 6, see attached database sheets and Hamann, bridging paragraph on page 1944; page 1944, Figure 1; page 1945, Figure 2; and Accession number P48960. Hamann also discloses four monoclonal antibodies (mAbs), BL-Ac/F2, VIM3, VIM3B and VIM3C that are reactive with the EGF-like domains of the CD97 molecule comprising SEQ ID NO: 1, 2 and 5. SEQ ID NO: 6 encompasses SEQ ID NO: 1, 2 and 5. Inherently, the disclosed antibodies would be immunologically cross-reactive to an antibody that is specifically reactive to the protein of SEQ ID NO: 6.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hamann et al. (Genomics 32: 144-147, February 1996/ IDS reference A2) as evidenced by Accession number P48960 (February 1, 1996/ IDS reference A8), in view of Campbell (Monoclonal antibody technology, Chapter 1, pages 1-32, 1984, New York, NY). Hamann as evidence by Accession #P48960 teaches the amino acid sequence of CD97, which encompasses SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 5 and SEQ ID NO: 6. Hamann does not teach an antibody composition that that binds to a soluble CD97 α1 or α2 selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 2 and SEQ ID NO: 5, which also binds the protein of SEQ ID NO: 6.

However, Campbell teaches a strategy to generate antibodies, as well as methods for producing hybridomas, procedures of monoclonal antibody production in mice and monoclonal antibodies from hybridoma cell lines with high biological activity (e.g. affinity, specificity, etc.), see page 3, Figure 1.1. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the teachings of both, Hamann and Campbell. Campbell states on page 29, Section 1.3.4 "It is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)." One of ordinary skill in the art would have been motivated to immunize an animal, such as a rat with any of the proteins designated as SEQ ID NO: 1, 2 or 5 to aid in the establishment of hybridomas secreting antibodies

able to bind with high specificity. These antibodies would inherently be immunologically cross-reactive to an antibody that is specifically reactive to the protein of SEQ ID NO: 6.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4315.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
5 January 2003